REMARKS

Claims 22, 25-27, 29-48 are pending in the application.

Rejections Withdrawn

The Applicant notes that the previous rejection of claims 22, 25-27, 29-48 under 35 U.S.C. 103(a) as being unpatentable over Yeager et al. (WO 01/51053, publication date 19 July 2001) in view of Kifor et al. (U.S. 5,958,884) and the rejection of claims 22, 25-27,29-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeager et al. (US 2002/0045665, publication date Apr 18 2002) in view of Kifor et al. (U.S. 5,958,884) have been withdrawn.

New Rejections

35 U.S.C. §103(a), quoted in the rejection, requires an evaluation of whether "the differences between the subject matter sought to be patented and the prior art are such that the **subject matter as a whole** would be obvious **at the time the invention was made** to **a person having ordinary skill in the art** to which said subject matter pertains. . ." (*emphasis added*). The subject matter as a whole reduces, then, to the distinguishing features clearly incorporated into the claims. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459, 473 (1966). The Supreme Court has recently re-affirmed the *Graham* analysis. "[T]he scope and content of the prior art are ... determined; differences between the prior art and the claims at issue are ... ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1388 (U.S. 2007).

Claim Rejections under 35 U.S.C. §103(a)

1). Claims 22, 25-27, 29-48 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sallis et al. (U.S. 7,405,222, effective filing date of January 25, 2002) in view of Yeager et al. (WO 01/51053, publication date 19 July 2001). The Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) of Claims 22, 25-27, 29-48 is unwarranted and requests that the rejection be withdrawn.

Sallis et al. discloses methods and compositions for the treatment of male sexual dysfunction by administering a pharmaceutical composition effective to cause said male to sustain an erection. The composition is formulated based on diagnostic assessment and an individualized formulation test step. Sallis et al., abstract. As the Examiner admits, the Sallis et al. reference does not teach the administration

of the composition meatally or the semi-solid composition comprising anesthetic as claimed in claim 22. Office Action, page 3, lines 6-7.

The Sallis et al. reference mentions premature ejaculation or PE only in passing seven times in the specification, at column 1, lines 26-27, column 3, line 19, column 4, line 64, column 6, line 67, column 7, line 39, column 11, line 51 and Fig. 2.

The Examiner alleges that the Sallis et al. reference teaches a method of treating premature ejaculation comprising administering a vasodilator such as prostaglandin E_1. However, the disclosures of the Sallis et al. reference are internally contradictory on the point of whether the composition taught for the diagnosis and treatment premature ejaculation, F6 (Sallis et al., Chart 2), does or does not contain prostaglandin E_1.

The Sallis et al. reference discloses three types of compositions. The first type includes compositions formulated with prostaglandin E_1 as the only vasodilator, composition F0. Sallis et al. column 5, lines 54-55. The second type includes compositions such as F4 that are formulated without prostaglandin E_1, but contain papaverine, phentolamine, atropine, and that are characterized as not requiring refrigeration. Sallis et al. column 5, lines 54-55. The Sallis et al. reference explains:

> When PGE1 is used without the other components, it is not stable in water at room temperature although for practical purposes it may be at room temperature for short periods of time. Similarly, formulations containing PGE1, papaverine, phentolamine and atropine, should be kept under refrigeration. A combination of papaverine, phentolamine and atropine can be stored without refrigeration. Sallis et al., column 6, lines 25-32.

The third type of composition includes compositions formulated with prostaglandin E_1 in combination with various amounts of papaverine, phentolamine, or atropine, compositions F1, F2, F3, and F5. Sallis et al. column 5, line 61 to column 6, line 13.

The descriptions of composition F6 are contradictory. F6 is stated to be "diluted F4 (i.e., non-refrigerated), for use with PE patients" in Chart 2 (Fig. 2). However, F6 is also described as "F6 **can** be a diluted version of F2, containing the same four vasodilators, e.g., at half-strength." Sallis et al., column 6, lines 6-7, *emphasis added.* See also column 10, lines 26-32. The Sallis et al. reference points to Chart 2 as the source for teachings regarding the diagnosis and treatment of premature ejaculation:

> The prescribed dosage table (Chart 2) also contains columns to separate patients with erectile dysfunction (ED) and those with premature ejaculation (PE). The reason for this separation is that patients with PE tend to require a more conservative adjustment than those with ED. Sallis et al. column 10, lines 49-53.

A careful review of the file history of the Sallis et al. reference and the priority document USSN 60/351,634 provided no further evidence to resolve the contradictory descriptions of composition F6 in the Sallis et al. reference. Therefore, the Applicant submits that there is **no unambiguous teaching** of the Sallis et al. reference regarding the diagnosis or treatment of premature ejaculation using compositions containing prostaglandin E_1.

Given the ambiguity of the teaching of the Sallis et al. reference on the diagnosis or treatment of premature ejaculation using compositions containing prostaglandin E1, the Applicant respectfully submits there is no unequivocal basis in fact for assertions such as "Sallis et al. teach a method of treating premature ejaculation comprising administering a vasodilator such as Prostaglandin E1" (Office Action, page 6, lines 10-11), or "The [Sallis et al.] reference teaches administration of prostaglandin in a method of treatment of premature ejaculation" (Office Action, page 7, lines 19-20), or "One of ordinary skill in the art would have been motivated to administer the composition of Yeager in a method of treatment of premature ejaculation in expectation of success because Sallis teach administration of prostaglandin E1 in a method of treating premature ejaculation . . ." (Office Action, page 7, last line, to page 8, 19-20).

In the Amendment and Response filed on September 26, 2008, at page 6, lines 1-4, the Applicant submitted that the level of ordinary skill in the art would be that of a clinician (M.D. or D.O.) treating patients suffering from sexual dysfunctions, including premature ejaculation, or that of a pharmaceutical chemist (Ph.D. or D.Sc.) seeking to develop a medication for the treatment of premature ejaculation. The Examiner has not traversed this characterization of the level of ordinary skill in the art. The Applicant submits that one of ordinary skill in the art would recognize the internal contradiction in the teachings of the Sallis et al. reference regarding the diagnosis or treatment of premature ejaculation using compositions containing prostaglandin E_1, and would not rely on the teachings of the Sallis et al. reference in the area of diagnosis or treatment of premature ejaculation.

Even if there were an unambiguous teaching in Sallis et al. regarding the diagnosis or treatment of premature ejaculation using compositions containing prostaglandin E_1, one of ordinary skill in the art would not be led to combine the teachings of the Sallis et al. reference and the teachings of the Yeager et al. WO 01/51053 reference to arrive at the presently claimed invention because the Sallis et al. reference teaches a different mode of administration than either the Yeager et al. WO 01/51053 reference or the presently claimed invention. The Yeager et al. WO 01/51053 reference and the present invention teach the non-traumatic application of the semisolid composition to the meatus of the penis into the naturally occurring space of the *fossa navicularis* of the penis. The Sallis et al. reference teaches the more invasive hypodermic injection of compositions into the corpora cavernosa of the penis.

The cited Yeager et al. reference, WO 01/51053, claims priority of USSN 09/480,738, which was filed on January 10, 2000, and which matured into U.S. Patent No. 6,323,241. The cited Sallis et al. reference claims the benefit of USSN 60/351,634, filed on January 25, 2002, and which was incorporated by reference in the cited Sallis et al. reference. Sallis et al. in USSN 60/351,634 refer to the Yeager et al. U.S. Patent No. 6,323,241 and meatal administration for the purpose of showing the drawbacks of the prior art. Sallis et al. USSN 60/351,634 at page 2, lines 23-29. The cited Sallis et al. reference also takes the position that another method, urethral placement of a suppository, has drawbacks, and that intracavernosal injection pharmacotherapy (ICP), practiced by the Sallis et al. reference, is preferable. Sallis et al. column 2, lines 4-21.

In summary, the Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) of Claims 22, 25-27, 29-48 over the combination of the Sallis et al. reference and the Yeager et al. WO 01/51053 reference is unwarranted and requests that the rejection be withdrawn.

2. Claims 22, 25-27, and 29-48 are rejected under 35 U.S.C. §103(a) as being unpatentable over Sallis et al. (U.S. 7,405,222, effective filing date of January 25, 2002) in view of Yeager et al. (US 2002/0045665, publication date April 18, 2002). The Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) of Claims 22, 25-27, 29-48 is unwarranted and requests that the rejection be withdrawn.

The Sallis et al. reference is discussed in detail above. The Yeager et al US2002/0045665 reference is stated on its face page to be a continuation-in-part of application No. 09/480,738, filed on Jan. 10, 2000, now Pat. No. 6,323,241, and a continuation-in-part of application No. PCT/US01/00852, filed on Jan. 10, 2001, which was published as WO 01/51053 on July 19, 2001. The teachings and suggestions of the Yeager et al. US2002/0045665 reference are thus substantially similar to the teachings and suggestions of the Yeager et al. WO 01/51053 reference discussed above.

For the reasons discussed above, the Applicant submits that there is **no unambiguous teaching** of the Sallis et al. reference regarding the diagnosis or treatment of premature ejaculation using compositions containing prostaglandin E_1. The Applicant submits that one of ordinary skill in the art would recognize the internal contradiction in the teachings of the Sallis et al. reference regarding the diagnosis or treatment of premature ejaculation using compositions containing prostaglandin E_1, and would not rely on the teachings of the Sallis et al. reference in the area of diagnosis or treatment of premature ejaculation, either alone, or in combination with the Yeager et al. US2002/0045665 reference.

The Examiner makes the following conclusory statement that is not supported by any facts of record:

> It would have been obvious to one of ordinary skill in the art at the time of the invention that composition comprising the same components as claimed when applied to the same set of population will have the same properties and function and hence the ejaculation latency time will be no less than two minutes or will be greater than two minutes and will be prolonged by at least two minutes as claimed in claims 44-46. Office Action, page 9, lines 9-14.

To the contrary, there is ample evidence in the record that the population of patients having premature ejaculation is heterogeneous, that premature ejaculation may have several etiologies, and a patient with premature ejaculation may also suffer from various other sexual dysfunctions. *See* the present application as filed, page 4, lines 6-28; Chia, S.J., Management of premature ejaculation - a comparison of treatment outcome in patients with and without erectile dysfunction, Int. Journal of Andrology, 2002, 25:301-305, of record, McMahon, C.G., et al., Disorders of Orgasm and Ejaculation in Men, J Sexual Medicine, 2004 Jul;1(1):58-65, of record, and Lue, T.F., et al., Summary of the recommendations on sexual dysfunctions in men, J Sexual Medicine. 2004 Jul;1 (1):6-23, of record. The McMahon et al. and Lue et al. references are summaries of recommendations presented at the 2nd International Consultation on Sexual Medicine in Paris, France, June 28-July 1, 2003.

For the reasons discussed in detail above, the Sallis et al. reference and the Yeager et al. US2002/0045665 reference, alone or in combination, neither teach nor suggest the presently claimed invention. The Applicant respectfully submits that the rejection of Claims 22, 25-27, 29-48 under 35 U.S.C. §103(a) based on the Sallis et al. reference and the Yeager et al. US2002/0045665 reference is unwarranted and requests that the rejection be withdrawn.

3. Claims 22, 25-27, 29-48 are rejected under 35 U.S.C. §103(a) as being unpatentable over Doherty et al. (U.S. 6,037,346) in view of Yeager et al. (WO 01/51053, publication date 19 July 2001). The Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) of Claims 22, 25-27, 29-48 is unwarranted and requests that the rejection be withdrawn. The Yeager et al. WO 01/51053 reference has been discussed above.

The Doherty, et al. reference, U.S. Patent No. 6,037,346, for "Local Administration Of Phosphodiesterase Inhibitors For The Treatment Of Erectile Dysfunction" relates to a method for treating erectile dysfunction in a mammalian male individual involving the local administration of a phosphodiesterase inhibitor or a pharmaceutically acceptable salt, ester, amide or derivative thereof within the context of an effective dosing regimen, where a preferred mode of administration is

transurethral. Doherty et al. Abstract. The Examiner notes that the Doherty et al. reference states that "the term 'erectile dysfunction' **is intended to include** any and all types of erectile dysfunction, including: vasculogenic, neurogenic, endocrinologic and psychogenic impotence, Peyronie's syndrome; priapism, premature ejaculation (PE) and any other condition, disease or disorder, regardless of cause or origin, which interferes with at least one of the three phases of human sexual response, i.e., desire, excitement and orgasm (col. 5, lines 42-54)." Office Action, page 10, lines 1-6 (*emphasis added*). The Examiner then states that "An applicant is entitled to be his or her own lexicographer (see MPEP 2111.01)."

The principle that an applicant is entitled to be his or her own lexicographer is a rule of claim construction that is employed as an exception to the general practice that terms in a claim are given the their ordinary and customary meaning.

> "[T]he ordinary and customary meaning of a claim term is the **meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention,** i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 75 USPQ2d 1321, 1326 (Fed. Cir. 2005) (en banc). *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)("In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art."). MPEP 8th, Rev. 6, page 2100-39, right column.

The principle that an applicant is entitled to be his or her own lexicographer is a rule of claim construction that recognizes that the terms that the applicant uses **to define the intended scope of the claims** do not have the meaning that the terms would have to a person of ordinary skill in the art in question at the time of the invention.

> An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (inventor may define specific terms used to describe **invention**, but must do so "with reasonable clarity, deliberateness, and precision" and, if done, must "'**set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change" in meaning**) (quoting *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387-88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)). MPEP 8th, Rev. 6, page 2100-41, left column.

The Applicant respectfully submits that while the principle that an applicant is entitled to be his or her own lexicographer may be relevant to construction of the claims of the Doherty et al. U.S. Patent No. 6,037,346, invoking that principle in the present context is an admission that the Doherty et al.

definition of 'erectile dysfunction' the is contrary to the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. One of ordinary skill in the art would apply the art-recognized definition of "erectile dysfunction" which is different from the art-recognized definition of "premature ejaculation." *See* the present application as filed, page 1, line 9, to page 3, line 29; Chia, S.J., Management of premature ejaculation - a comparison of treatment outcome in patients with and without erectile dysfunction, Int. Journal of Andrology, 2002, 25:301-305, of record, McMahon, C.G., et al., Disorders of Orgasm and Ejaculation in Men, J Sexual Medicine, 2004 Jul;1(1):58-65, of record, and Lue, T.F., et al., Summary of the recommendations on sexual dysfunctions in men, J Sexual Medicine. 2004 Jul;1 (1):6-23, of record. The McMahon et al. and Lue et al. references are summaries of recommendations presented at the 2nd International Consultation on Sexual Medicine in Paris, France, June 28-July 1, 2003.

For the reasons discussed in detail above, the Doherty et al. reference and the Yeager et al. WO 01/51053 reference, alone or in combination, neither teach nor suggest the presently claimed invention. The Applicant respectfully submits that the rejection of Claims 22, 25-27, 29-48 under 35 U.S.C. §103(a) based on the Doherty et al. reference and the Yeager et al. WO 01/51053 reference is unwarranted and requests that the rejection be withdrawn

4. Claims 22, 25-27, 29-48 are rejected under 35 U.S.C. §103(a) as being unpatentable over Doherty et al. (U.S. 6,037,346) in view of Yeager et al. (US 2002/0045665, publication date April 18, 2002). The Applicant respectfully submits that the rejection under 35 U.S.C. §103(a) of Claims 22, 25-27, 29-48 is unwarranted and requests that the rejection be withdrawn. Both the Doherty et al. reference and the Yeager et al. US 2002/0045665 reference have been discussed in detail above. The Applicant submits that the Doherty et al. reference and the Yeager et al. US 2002/0045665 reference, alone or in combination, neither teach nor suggest the presently claimed invention, and the rejection of Claims 22, 25-27, 29-48 under 35 U.S.C. §103(a) based on the Doherty et al. reference and the Yeager et al. US 2002/0045665 reference is unwarranted, and should be withdrawn.

Conclusion

In light of the amendments and arguments presented herein, the Applicant respectfully submits that all pending claims are in condition for allowance and requests a timely Notice of Allowance to follow in this case. This paper is being filed timely as it is being filed with a request for a three month extension of time and appropriate fees. In the event any additional extensions of time, fees and/or credits are necessary, please consider this a conditional petition therefor. The undersigned hereby authorizes the requisite fees to be charged and/or credited accordingly to Deposit Account No. 50-1582.

If at any time a telephone discussion would assist the Examiner and/or advance prosecution, please contact the undersigned at 508-860-1472 (direct line).

Respectfully submitted,

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